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A safety and efficacy trial of lethally irradiated allogeneic pancreatic tumor cells transfected with the GM-CSF gene in combination with adjuvant chemoradiotherapy for the treatment of adenocarcinoma of the pancreas.

Sub-category: Translational research

Category: Pancreas, Small Bowel, and Hepatobiliary Tract Meeting: 2007 Gastrointestinal Cancers Symposium

Abstract No: 106

Author(s): D. Laheru, C. Yeo, B. Biedrzycki, S. Solt, E. Lutz, B. Onners, I. Tartakovsky, R. Hruban, S. Piantadosi, E. Jaffee

Abstract:

Introduction: Pancreatic cancer remains the fourth leading cause of cancer related deaths in the US. Surgical resection provides the only possibility of cure. Five-year survival remains approximately 15% to 20% with 1- and 2-year survival of 63% and 42% respectively. A standard adjuvant treatment approach for patients with resected disease has not yet been determined. We have developed an irradiated GM-CSF transfected allogeneic whole cell line pancreas adenocarcinoma immunotherapy and previously reported a follow-up 60 patient study in this same population using the highest bloactive immunotherapy dose identified in the initial phase I study. **Methods:** Single institution phase II study of 60 patients with resected pancreatic adenocarcinoma administered a total of five immunotherapy treatments using two pancreatic cancer cell lines each delivering 2.5 X 10° cells ID. Immunotherapy treatment one was administered 8 to 10 weeks following surgical resection. Patients subsequently were treated with 5-FU CI based chemotherapy integrated with radiotherapy. Patients who were disease-free 1 month after completion of chemoradiotherapy received immunotherapy treatment 2-4, each 1 month apart. A fifth and final booster immunotherapy treatment was administered 6 months after vaccine 4. Results: Median follow-up for these patients was approximately 32 months. 1) The administration of a GM-CSF allogeneic pancreas cancer vaccine is safe and well tolerated. Treatment related side effects included transient vaccine injection site reactions. 2) At this early analysis, the 1- and 2-year survival are 88% and 76% respectively. While the data is only preliminary, this study compares very favorably with the available published data. 3) Follow-up survival data with median follow-up approaching 3 years and a matched cohort analysis comparing patients enrolled on this adjuvant vaccine study to the Johns Hopkins Surgery database will be presented at this meeting.

### Associated Presentation(s):

1. A safety and efficacy trial of lethally irradiated allogeneic pancreatic tumor cells transfected with the GM-CSF gene in combination with adjuvant chemoradiotherapy for the treatment of adenocarcinoma of the pancreas

Meeting: 2007 Gastrointestinal Cancers Symposium

Presenter: Daniel Laheru, MD

Session: General Session III: Translational Research (General Session)



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No presentation available

Meeting: 2007 Gastrointestinal Cancers Symposium

Presenter: Daniel Laheru, MD

Session: General Poster Session D (Poster Presentation)

## Other Abstracts in this Sub-Category

1 impact of NAT1 polymorphism on survival of pancreatic cancer.

Meeting: 2007 Gastrointestinal Cancers Symposium Abstract No: 107 First Author: A. K. Nooka Category: Pancreas, Small Bowel, and Hepatobiliary Tract - Translational research

2. Radiosensitization of human pancreatic cancer through protein kinase Cβ: (PKCβ:)-mediated suppression of the GSK3β:/β:-catenin Axis.

Meeting: 2007 Gastrointestinal Cancers Symposium Abstract No: 203 First Author: A. Spalding Category: Pancreas, Small Bowel, and Hepatobiliary Tract - Translational research

3. Targeting transforming growth factor β: (ΤΘFβ:) type I receptor (Τβ:RI) kinase activity: A therapeutic approach to suppress metastatic processes in human pancreatic cancer (HPC).

Meeting: 2007 Gastrointestinal Cancers Symposium Abstract No: 204 First Author: D. Melisi

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 A safety and efficacy trial of lethally irradiated allogeneic pancreatic tumor cells transfected with the GM-CSF gene in combination with adjuvant chemoradiotherapy for the treatment of adenocarcinoma of the pancreas.

Meeting: 2007 Gastrointestinal Cancers Symposium. Abstract No: 106 First Author: <u>D. Laheru</u> Category: Pancreas, Small Bowel, and Hepatobiliary Tract - <u>Translational research</u>

Adjuvant chemoradiation therapy after pancreaticoduodenectomy for intraductal papillary mucinous neoplasm of the
pancreas with associated invasive carcinoma.

Meeting: 2007 Gastrointestinal Cancers Symposium Abstract No: 178 First Author: M. J. Swartz Category: Pancreas, Small Bowel, and Hepatobiliary Tract - <u>Multidisciplinary Treatment</u>

A multicenter phase 2 consortium (P2C) study of triapine in patients (pts) with advanced adenocarcinoms of the pancreas.
 Meeting: 2006 ASCO Annual Meeting. Abstract No: 14118. First Author: D. L. Groteluschen.
 Category: Gastrointestinal (Noncolorectal) Cancer - Pancreatic Cancer

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1. A safety and efficacy trial of lethally irradiated allogeneic pancreatic tumor cells transfected with the GM-CSF gene in combination with adjuvant chemoradiotherapy for the treatment of adenocarcinoma of the pancreas

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#### Journal of Clinical Oncology Articles by D. Laheru

Novel allogeneic granulocyte-macrophage colony-etimulating factor-secreting tumor vaccine for pancreatic cancer: a
phase I trial of safety and immune activation.

J Clin Oncol, United States Vol 19, No 1 (1/3/2001): pp. 145-56

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PubMed Articles by D Laheru





Immunohistochemical and genetic evaluation of deoxycytidine kinase in pancreatic cancer: relationship to
molecular mechanisms of gemoitabine resistance and survival.

Clin Cancer Res, United States Vol 12, No 8 (4/28/2006); pp. 2492-7 PMID: 16638857 [PubMed - in process]

Omega-3 fatty acids for the treatment of cancer cachexia: issues in designing clinical trials of dietary supplements.

J Altern Complement Med, United States Vol 11, No 6 (1/10/2006): pp. 1039-46 PMID: 16398596 [PubMed - in process]

 Pancreaticoduodenectomy With or Without Distal Gastrectomy and Extended Retroperitoneal Lymphadenectomy for Periampullary Adenocarcinoma-Part 3: Update on 5-Year Survival.

J Gastrointest Surg,

Vol 9, No 9 (12/8/2005): pp. 1191-1206 PMID: 16332474 [PubMed - in process]

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